Early detection of pulmonary exacerbations in mucociliary clearance diseases: Molecular fingerprinting by exhaled breath and microbiome analysis

Published: 03-12-2012
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Objectives: The primary objective is to establish whether expiratory VOC analysis by electronic nose and GC-MS can: Ia) discriminate between patients (CF, PCD) with and without an exacerbation and Ib) discriminate between different microbial species...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON41268

Source
ToetsingOnline

Brief title
Early detection of exacerbations in mucociliary clearance diseases

Condition

- Respiratory disorders congenital
- Respiratory tract infections

Synonym
Cystic Fibrosis, Primary Ciliary Dyskinesia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Merieux instituut

Intervention

Keyword: CF, Exhaled breath, Microbiome, PCD

Outcome measures

Primary outcome

Primary outcome measures: relative changes in electronic nose sensors,

retention time, abundance and mass to charge ratio from GC-MS analysis.

Secondary outcome

Secondary outcomes: (change in) bacterial diversity.

Study description

Background summary

Chronic infection and inflammation of the airways are the leading causes of morbidity in cystic fibrosis (CF) and primary ciliary dyskinesia (PCD). Early detection and vigorous treatment of exacerbations are important in preserving lung function and quality of life in these patients. Further, a better understanding of airway infections and the development of exacerbations could provide opportunities for novel strategies to maintain lung health. In this longitudinal study, we investigate the dynamics of airway and intestinal bacterial communities and exhaled volatile organic compounds. We aim to test whether respiratory exacerbations in CF and PCD patients can be detected by changes in the microbiome and molecular pattern recognition of volatile organic compounds in exhaled breath.

Study objective

Objectives: The primary objective is to establish whether expiratory VOC analysis by electronic nose and GC-MS can:
Ia) discriminate between patients (CF, PCD) with and without an exacerbation and
Ib) discriminate between different microbial species

The secondary objective is to establish the dynamics of bacterial diversity in the airways and intestines of patients with CF and PCD during stable disease and during an exacerbation.

Study design

Longitudinal observational study during one year with collection of 5 exhaled breath and microbiology samples.

Study burden and risks

The burden for the patients with CF and PCD in this longitudinal study is limited to 3-monthly collection of sputum or cough swab samples, an exhaled breath sample and a faeces sample. These measurements are completely safe and without any health risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

* CF diagnosis is based on: clinical symptoms in combination with an abnormal sweat test (chloride > 60 mmol/l) and/or identification of mutations in both alleles of the CFTR gene.
* PCD diagnosis is based on: a combination of clinical symptoms, abnormal movement of cilia on microscopic evaluation of respiratory epithelial biopsies and epithelial cell cultures, or identification of an ultra structural defect in the cilia by electron microscopy.
* * 6 years of age
* Stable respiratory disease for at least 6 weeks (as determined by the treating physician)
* Ability to perform lung function measurement

Exclusion criteria

* Mental retardation
* Diabetes Mellitus (CF complication)
* Technical unsatisfactory performance of measurements
* On the waiting list for lung transplantation
* Participation in the PREVEC or VERTEX study (AMC)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2013
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	03-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41939.018.12
Other	NTR voorlopig candidate number 13329